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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,470	05/24/2001	Robert G. Lukasik	JOHNA.053A	2982
27777	7590	08/10/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			JASTRZAB, KRISANNE MARIE	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/864,470

Applicant(s)

LUKASIK ET AL.

Examiner

Krisanne Jastrzab

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1-2003</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-11, 17-22 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 3, 6, 17-18 and 27-28, these claims are found to be vague and indefinite because they improperly attempt to define a structural element by itself, namely the "volume". Clarification of the definition of the "volume" is required.

With respect to claims 7 and 11, these claims are found to be vague and indefinite for improperly attempting to define the apparatus by itself, namely in the reference in the body of these claims to "the adjustable accumulator". Correction is required.

With respect to claim 10, this claim is found to be vague and indefinite because it improperly attempts to further limit the "chemical" for use with the accumulator, however, the "chemical" was not positively provided in the body of the claim and therefore cannot be further limited.

Further with respect to claims 6, 18 and 28, these claims are found to be vague and indefinite because they set forth "at least two compartments", then continue to define "said compartment" and thus is it not clear if both of "at least

Art Unit: 1744

two compartments" must meet the limitation thereafter or if another compartment is being set forth. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Howe U.S. patent No. 5,259,370.

Howe teaches a nebulizer heater for delivering an aerosol having an improved accumulator. The accumulator is formed of concentric, partitioned cylinders and adjusts to control the aerosol delivery (see column 11, lines 29-68 and column 12, lines 28-65). The partition is formed to slope toward the inner tube and an o-ring is provided for effective containment of the liquid. See Figs. 10 and 11. It is taught that the elements of the accumulator are detachable (column 8, lines 43-62).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-20 and 22-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Childers et al., U.S. patent No. 5,527,507 in view of Howe '370 as applied above.

Childers et al., teach a sterilization system for sterilizing articles with hydrogen peroxide vapor wherein the liquid hydrogen peroxide is supplied through an accumulator in order to provide accurate, reproducible amounts of sterilant. The system includes a source of hydrogen peroxide liquid, a

Art Unit: 1744

sterilization chamber with a vacuum pump means in order to evacuate the chamber prior to the introduction of the hydrogen peroxide vapor. The system is taught as useful with any know sterilization cycle. See column 2, lines 63 through column 3, line 15, column 4, lines 52-61, and column 5, lines 15-63.

It would have been obvious to one of ordinary skill in the art to utilize the accumulator construction of Howe in the system of Childers et al., because it would provide for delivery of accurate, reproducible amounts of sterilant which can be accurately and reproducibly adjusted for the chosen sterilization cycle or load.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Childers et al., together with Howe as applied to claims 16-20 and 22-33 above, and further in view of Jacobs U.S. patent No. 4,756,882.

Jacobs teaches the conventionality of plasma sterilization with hydrogen peroxide as a known sterilization cycle.


It would have been well within the purview of one of ordinary skill in the art to utilize the system of the combination above with any know sterilization cycle as indicated by Childers, including a known plasma cycle such as identified by Jacobs.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Krisanne Jastrab
Primary Examiner
Art Unit 1744

August 9, 2004